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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,973	03/01/2002	Kesavan Esuvaranathan	488002000200	6742

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,973	ESUVARANATHAN ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-16,18-31,33,34,36-41,43,44,46-57 and 59-65* is/are pending in the application.

4a) Of the above claim(s) *1,3-16,18-31,33,34,36-41,43,44,46-56 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57,59-61 and 63-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2002* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/2905;10/3/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

An amendment was received and entered on 7/5/05.

Claims 2, 17, 32, 35, 42, 45, and 58 were canceled.

Claims 1, 3-16, 18-31, 33, 34, 36-41, 43, 44, 46-57, and 59-65 are pending in the application.

Claims 1, 3-16, 18-31, 33, 34, 36-41, 43, 44, 46-56 and 62 were withdrawn from further consideration in the Action of 3/22/05 pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/22/04.

Claims 57, 59-61, and 63-65 are under consideration in this Office Action.

Claim 65 was erroneously omitted from the list of pending claims in the previous Action mailed 3/22/05, but was rejected under 35 USC 103 in that Action. Applicant responded to the rejection.

Priority

The Declaration for Utility Patent Application filed 3/12/02 claims priority under 35 USC 120 or 365(c) to PCT/SG00/00130, filed 9/1/2000, and to Australian Application PQ2593/99, filed 9/1/1999.

The as filed specification did not state the relationship between PCT/SG00/00130 and the instant application. So priority was denied in the previous action. In the response filed 7/15/05, Applicant amended the specification to include the relationship of PCT/SG00/00130 to the instant application. However, this amendment was not

submitted within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application, and no petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c) was filed. As a result the priority claim under 35 USC 120 remains denied. See below.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of

such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

The Application Data Sheet (ADS) filed 3/12/02, claims foreign priority to PCT/SG00/00130, filed 9/1/2000, and to Australian Application PQ2593/99, filed 9/1/1999. Priority claims under 35 USC 119 (a-d) to these documents are denied because no certified copy of the documents have been received by the Office, and because the applications were filed greater than 1 year prior to the instant application.

Claim Objections

Applicant's amendment overcame the objection to claim 63.

Compliance with Sequence Rules

Applicant's submission of a paper copy of the Sequence Listing and statement that the content of the paper and computer readable copies are the same and the submission includes no new matter places the application in compliance with the requirements of 37 CFR 1.821 through 1.825.

Specification

The amendment filed 3/1/02 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention.

The application was filed on 3/1/02, together with a preliminary amendment and a Declaration for Utility Patent Application. The preliminary amendment added a priority claim to PCT/SG00/00130, and incorporated that document in its entirety. However, the

Declaration for Utility Patent Application did not indicate that the specification as filed was amended. As a result, the preliminary amendment indicating incorporation by reference of PCT/SG00/00130 is new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57 and 59-61 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lawrencia et al (Conference Supplement to Cancer Gene Therapy, Gene Therapy of Cancer VII, 12/1999), as evidenced by Lawrencia et al (Gene Therapy (8: 760-768, 2001).

Lawrencia (1999) taught a composition comprising DNA and DMBC. DMBC was defined as the cationic lipid DOTAP, and "two additives". Lawrencia (2001) disclosed that DMBC is DOTAP + methyl-beta-cyclodextrin solubilized cholesterol. Absent evidence to the contrary the DMBC of Lawrencia (1999) is the same as the DMBC of Lawrencia (2001). See abstract. So, Lawrencia (1999) taught a polynucleotide, DOTAP and methyl-beta-cyclodextrin solubilized cholesterol.

Response to Arguments

Applicant's arguments filed 7/25/05 have been fully considered but they are not persuasive.

At page 14 of the response Applicant asserts that the cited references were published after the priority date for the instant application. This is unpersuasive because the priority claims are denied for the reasons set forth above under Priority. Note that the date of the Lawrencia (2001) reference is irrelevant because it was relied upon only as evidence of what was taught in the Lawrencia (1999) reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 57 and 63 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lawrencia et al (Conference Supplement to Cancer Gene Therapy, Gene Therapy of Cancer VII, 12/1999) in view of Woodle et al (US 20030166601, published 9/4/03).

Lawrencia (1999) taught a composition comprising DNA, DOTAP, and methyl-beta-cyclodextrin solubilized cholesterol as discussed above.

Lawrencia did not teach the cationic lipids DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, or DOPC.

Woodle taught that DOTAP, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, and DOPC were cationic lipids that were interchangeable in nucleic acid delivery compositions. See paragraphs 20, 97, 98, and claim 16. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute any of the cationic lipids of Woodle for DOTAP in the nucleic acid delivery composition of Lawrencia.

Claims 57, 64, and 65 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Felgner et al (US Patent 5580859, issued 3/18/94) in view of Lawrencia et al (Conference Supplement to Cancer Gene Therapy, Gene Therapy of Cancer VII, 12/1999).

Felgner taught compositions comprising DOTAP and plasmid DNA, antisense oligonucleotides, phosphorothioate oligonucleotides, RNA molecules and ribozymes for transfection of bladder cells. See abstract, detailed description paragraphs 2, 55, and 126.

Felgner did not teach a composition comprising cyclodextrin solubilized cholesterol.

Lawrencia (1999) taught a composition comprising DNA, DOTAP, and methyl-beta-cyclodextrin solubilized cholesterol as discussed above for transfection of bladder cells.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the composition of Lawrencia to deliver the nucleic acids of Felgner to bladder cells. One would have been motivated to do so because Lawrencia taught that DOTAP combined with beta-cyclodextrin solubilized cholesterol is an effective agent for transfection of urothelial cells in vivo or in vitro. See conclusion.

Response to Arguments

Applicant's arguments filed 7/25/05 have been fully considered but they are not persuasive.

At page 14 of the response Applicant asserts that the cited references were published after the priority date for the instant application. This is unpersuasive because the priority claims are denied for the reasons set forth above under Priority.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.